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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
12/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,303	ROTHENBERG ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-34,36 and 38-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-34,36 and 38-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 May 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/302009 has been entered.

Status of the claims

2. In the claim set submitted with the request for continued examination filed on 09/30/2009 Applicant amended claims 25, 30-32, 36 and 44 and cancelled claims 35, 37 and 45. Claims 25-34, 36, and 38-44 are pending and are currently examined.

Withdrawn claim rejections

3. The rejection of claims 25-34, 36, 38-39, 41 and 44 under 35 U.S.C. 103(a) as being unpatentable over Hoier-Madsen et al., (Int. J. Tiss Reac. X1(6), 327-332, 1989) ("Hoier-Madsen"- cited in the previous Office actions) in view of Brown JL (U. S. Pat. No. 6,852,546- Brown '546) and Da Costa et al. (Biochim. Biophys. Acta, 1292, 23-30, 1996) ("Da Costa"- cited in the previous Office actions) is withdrawn in view of the amendments to the claims.

4. The rejection of the claims 40, 42 and 43 under 35 U.S.C. 103(a) as being unpatentable over Hoier-Madsen et al., (Int. J. Tiss. Reac. X1(6), 327-332, 1989) ("Hoier-Madsen"- cited in the previous Office actions) in view of Brown JL (U. S. Pat. No. 6,852,546- Brown '546) and Da Costa et al. (Biochim. Biophys. Acta, 1292, 23-30, 1996) ("Da Costa"- cited in the previous Office actions) and in further view of Yu et al. (U.S. Pat. No. 6,406,867- cited in the previous Office actions)) is withdrawn in view of the amendments to the claims.

5. The rejection of claims 25-36 and 38 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps (the steps recited in claim 35 are needed before the step a) in the independent claim 25) is withdrawn in view of the amendment to the claims.

Drawings

6. The drawings are objected to because figures 9-11 are extremely hard to read and details are faded. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. In the independent claim 25, the omitted step is: measuring the affinity of the autoantibody for apoFR. Since the method is specifically envisioned for detecting the affinity, the final step is missing and thus the goal of the method is not achieved. Claims 26-34 are rejected as dependent claims.

9. Claims 36 and 38-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The independent claims 36 and 44 require, as components of the kit it claims, a known human *autoantibody* to FR as a positive control and also the biological sample from a subject. It is unclear how can the kit may comprise a known human autoantibody since there was no known isolated human

autoantibody to FR at the time that the invention was made and even today there is no standard autoantibody to be used as a positive control. Also, it is unclear how a kit comprising elements that are supposed to be used in the method for detection of the affinity of the autoantibodies to a folate receptor for multiple subjects may contain the biological sample of the subject to be investigated with the said kit.

The claims 38-43 are rejected as dependent claims.

Further, claim 44 is indefinite because it contains in subheader a), the recitation: "an amount of purified human FR associated immobilized to a substrate". The specification does not explain the meaning of the recitation and the Examiner could not understand what is claimed. As such, the metes and bounds of the claim could not be determined.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36 and 38-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The independent claims 36 and 48 are drawn to a test kit for detecting the affinity of autoantibodies to a folate receptor (FR) in a sample obtained from a subject comprising:

- a detectable amount of purified human apo-FR
- an anti-human immunoglobulin molecule conjugated to an enzyme or to a fluorescent compound;
- a known human autoantibody to FR as a positive control, and a known control antibody that does not bind to FR.

The claims require the kit to contain a known human autoantibody to FR as a positive control. There no requirement regarding the structure and provenience of the human *autoantibody* to FR as long it is known. There is no specific epitope to which the required antibody is supposed to bind. Thus the claims are drawn to kits that contain a genus of antibodies defined only by the protein that is binding and the word "known".

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

In this case, the antibody comprised by the kit is defined only by the protein that is binding and the word "known". The examiner is interpreting the word "known" as "to be in the hands of the public". The autoantibody cannot be in the possession of the

public until the method of measuring the affinity claimed in claim 25 is brought to completion. It is also considered that the nature antibody, being an autoantibody, is unique to each human patient and cannot be known *a priori*. Also, up to the present day, there is no commercial human autoantibody to FR. The specification does not present any other description of the mode of obtaining a human autoantibody to FR but from the patient to be tested. Even considering, in arguendo, that a patient has, after detection, an autoantibody to FR, there is no know case of extracting human autoantibodies and using them in a kit as a general "known" (and generic, standard) human autoantibody.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics and the fact that the antibody in question would be in the hands of the public only after the completion of the invention, the specification does not provide adequate written description of the claimed genus. .

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. See *Fiers v. Revel*,

25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Conclusion

11. Applicants' representative, Mr. Peter Bernstein, was contacted telephonically on December 1st and notified that the Application would be allowable if the missing step would be inserted in the method claims and the kit claims would be cancelled. Applicant declined the offer. Thus, no claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elly-Gerald Stoica/

Examiner, Art Unit 1647